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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,939	12/17/2001	Prakash Kadkade	31699.0086	2933

21967 7590 08/11/2005

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,939

Applicant(s)

KADKADE, PRAKASH

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,22,23,25,61-63 and 65-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,22,23,25,61-63 and 65-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/05</u> . | 6) <input type="checkbox"/> Other: _____ |

S.O.D

DETAILED ACTION

Claims 1-8, 22-23, 25, 61-63 and 65-75 are presented for reconsideration on the merits.

Response to Amendment Papers

The amendment of May 26, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 26, 2005, was filed after the mailing date of the action on January 26, 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 22 and 61-63 and 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panis et al in view of Fretz et al, EP 0 147 236, Cino et al and **newly cited** Goodrich Jr. et al (US Patent No. 5,800,978 cited on enclosed PTO-892 Form).

Claims are drawn to a method for recovering plant cells from cryopreservation comprising obtaining cryopreserved plant cells, thawing the cells, washing the cells in a medium comprising at least one cryoprotectant agent to reduce its amount, and a stabilizer and removing the agent and recovering the thawed plant cells. The plant cells can be of the genus species *Taxus brevifolia* or *Musca* or *Picea* or *Daucus* or *Catharanthus*. Also a regrowth step can be carried out by the process. The agent can be glycerol or DMSO in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to about 20% by weight. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute or can be at about 140 degrees Celsius per minute.

Panis et al teach obtaining cryopreserved plant cells, thawing the cells, and recovering the thawed plant cells, see page 337, all lines and entire document. The plant cells can be of the genus *Musca* or *Picea* or *Daucus* or *Catharanthus*, see pages 339, line 6, page 343, line 3, page 345, line 21, and page 348, lines 1-20. Also a regrowth step can be carried out by the process, see page 337, line 24. The agent can be a carbon source such as glycerol or it can be DMSO, wherein the agent is in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to

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about 20% by weight, see page 340, lines 35-50. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute, see page 340, line 7. MS-salts are used for recovery also, page 340, line 22. Removal of the agent by washing is disclosed at page 340, lines 7-8. Thawing can occur above 40 degrees Celsius, see page 337, line 20.

Panis et al does not disclose incubation technique in a medium containing cryoprotectant and stabilizer or use of *Taxus brevifolia* plant cells.

Fretz et al teach incubation after thawing for regeneration of plant cells, see page 141, lines 1-21. Fretz et al at page 142, column 1, line 36, teach plating the thawed plant cells.

EP Patent 0 147 236 teaches regeneration of plant cells in a medium containing a stabilizer, such as silver nitrate and other well known inhibitors, and carbon sources such as sugars, note pages 6-7, all lines.

Cino et al teach a medium and culture therefore, of *Taxus brevifolia* cells, see column 2, lines 46-47.

Goodrich Jr. et al teach washing the cells after thawing, note column 31, lines 44-46.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a method for the recovery of cryopreserved plant cells as disclosed by Panis et al, using the washing technique of newly cited Goodrich Jr. et al and techniques of Fretz et al on a regeneration medium containing a stabilizer as disclosed by the EP Patent and further to select for *Taxus* plant cells as

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disclosed by Cino et al. The presence of cryoprotectants as disclosed by Panis et al in the medium of the EP Patent would have been expected to work because these agents can be selected from sugars and the medium of the EP Patent clearly teaches the presence of sugars to provide for a successful combination of ingredients for the recovery of plant cells. It should be noted that sugars are encompassed by cryoprotectants. To reduce the amounts of the cryoprotectants in the media via washing the cells after thawing is clearly within the skill of an ordinary artisan as disclosed by Goodrich Jr. et al.

One of skill in the art would have expected successful results with the combination of stabilizer and cryoprotectant in a medium because these two ingredients are disclosed by the cited prior art combination to be useful for recovering plant cells. The process steps are disclosed by Panis et al Goodrich Jr. et al and Fretz et al obtaining cryopreserved plant cells, thawing, washing, and removal of cryoprotectant and recovering thawed plant cells. The cells are not disclosed by the art to have been genetically or phenotypically altered in any way.

Further, the thawed cells are plated on a medium as disclosed by Fretz et al, see page 142, line 36. In addition, the cells can be pretreated. Further to select for a heating temperature of about 140 degrees Celsius is well within the skill of an artisan who is capable of ascertaining such optimal conditions. Also Panis et al clearly teach thawing temperatures of 40 degrees Celsius and above, see page 337, all lines. Successful results would have been expected based upon the reading of the

combination of cited prior art. In the absence of convincing and persuasive evidence to the contrary the claims are deemed prima facie obvious.

Response to Arguments

Applicant's arguments filed May 26, 2005, have been fully considered but they are not persuasive. The argument that washing and plating are not disclosed is noted, however, Goodrich et al clearly teach that washing cells after thawing is conventional in the art and furthermore, planting thawed cells is at least disclosed by Fretz et al, as discussed above. Further, the use of stabilizer to recover and regenerate plant cells clearly suggests a use of the same for thawed cells since to regenerate viability is clearly desirable to one of skill in the art. The use of a stabilizer would have been expected to provide successful results and the combination is obvious as suggested by the need and desire in this art to recover viability of cells that have been cryopreserved. Each of the process steps are at least suggested, if not taught, by the cited prior art combination and the claims are rendered prima facie obvious over the newly applied art combination of references.

Claims 23, 25 and 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panis et al in view of newly cited Goodrich Jr. et al (discussed above), Fretz et al, and EP 0 147 236.

In addition to the descriptions discussed above, the claims are additionally drawn to a medium having a divalent cation such as calcium, magnesium or manganese, and ethylene inhibitor such as silver salt or some other well known one can be used for

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recovering the plant cells. Further, a sucrose agent can be applied as a cryoprotectant agent.

Panis et al teach obtaining cryopreserved plant cells, thawing the cells, and recovering the thawed plant cells, see page 337, all lines and entire document. The plant cells can be of the genus *Musca* or *Picea* or *Daucus* or *Catharanthus*, see pages 339, line 6, page 343, line 3, page 345, line 21, and page 348, lines 1-20. Also a regrowth step can be carried out by the process, see page 337, line 24. The agent can be a carbon source such as glycerol or it can be DMSO, wherein the agent is in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to about 20% by weight, see page 340, lines 35-50. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute, see page 340, line 7. MS-salts are used for recovery also, page 340, line 22. Removal of the agent by washing is disclosed at page 340, lines 7-8. Thawing can occur above 40 degrees Celsius, see page 337, line 20. Sucrose is disclosed at page 340, last line. Further, DMSO is taught to play a role as a free radical scavenger, note page 345, lines 19-20.

Panis et al does not disclose incubation in a medium having at least one ethylene inhibitor and/or divalent cation.

Goodrich Jr. et al teach washing after thawing the cells, as discussed above.

Fretz et al teach incubation after thawing for regeneration of plant cells, see page 141, lines 1-21. Also Fretz et al teach plating after thawing plant cells, note page 142, column 1, line 36.

EP Patent 0 147 236 teaches regeneration of plant cells in a medium containing a silver salt, such as silver nitrate and other well known inhibitors, and carbon sources such as sugars, note pages 6-7, all lines. Further, divalent cations are disclosed, see page 6, lines 28, 29 and page 7, line 6.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a method of recovering cryopreserved plant cells as disclosed by Panis et al using different cryoprotective agents and an additional step of washing thawed plant cells, as disclosed by Goodrich Jr. et al, with the agents in a medium containing at least one silver salt, such as silver nitrate and other well known inhibitors in the art, and divalent cations as disclosed by Fretz et al and EP Patent 0 147 236, as well as plating the thawed plant cells, also disclosed by Fretz et al. Clearly one of skill in the art would have been motivated to combine these well known steps and ingredients in the art for the purpose of recovering plant cells. There is no unexpected successful result obtained by the claimed process of which each step of said process is disclosed by the cited prior art combination. Further, the removal of more than one cryoprotectant would have been expected to work via washing as well and several washings are disclosed to be useful by Goodrich et al. Therefore, in the absence of convincing and persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed May 26, 2005, have been fully considered but they are not persuasive. The argument that washing and plating are not disclosed is noted,

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however, Goodrich et al clearly teach that washing cells after thawing is conventional in the art and furthermore, planting thawed cells is at least disclosed by Fretz et al, as discussed above. Further, the use of stabilizer to recover and regenerate plant cells clearly suggests a use of the same for thawed cells since to regenerate viability is clearly desirable to one of skill in the art. The use of a stabilizer would have been expected to provide successful results and the combination is obvious as suggested by the need and desire in this art to recover viability of cells that have been cryopreserved. Each of the process steps are at least suggested, if not taught, by the cited prior art combination and the claims are rendered prima facie obvious over the newly applied art combination of references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-8, 22-23, 25, 61-63 and 65-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-48 of U.S. Patent No. 6,753,182. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because the claims of the instant are within the scope of the patented claims since washing as disclosed in claim 28 of the patented claims can be carried out after thawing. The removal of the cryoprotectant via washing would have been expected to reduce the concentration of at least one cryoprotectant in the media containing the plant cells. One of skill would have been motivated to carry out washings in order to remove cryoprotectant and recover the plant cells based on the patented claimed subject matter. Also the step of incubating is not necessarily omitted from the instant claims. One of skill would have been motivated to provide for the instant claims based on a reading of the patented claimed subject matter and hence the instant claims *prima facie* obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-1449 are cited to further show the state of the art.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
August 6, 2005